510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k120866

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose oxidase

E. Applicant:

Delbio Incorporation

F. Proprietary and Established Names:

DA01 Blood Glucose Monitoring System
DAC06 Glucose Control Solutions

G. Regulatory Information:

Device	Product Code	Classification	Regulation Section	Panel
DA01 Blood Glucose Monitoring System	NBW, CGA (over the counter)	Class II	21 CFR § 862.1345, glucose test system, over the counter, Glucose oxidase,	75-Chemistry
DAC06 Glucose Control Solutions	JJX	Class I, reserved	21 CFR § 862.1660, Quality Control material	75-Chemistry

H. Intended Use:

1. Intended use(s): See indications for use below.

2. Indication(s) for use:

DA01 Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) at home. It is used for quantitative measurement of glucose level in fresh capillary whole blood samples (from the finger and the palm). The alternative site testing can be only used during steady-state blood glucose monitoring. The DA01 blood glucose monitoring system is intended for use by a single person and should not be shared. In addition, it is intended for use at home as an aid in monitoring the effectiveness of diabetes control program. It should not be used for the diagnosis or screening of diabetes, nor for the testing of neonates.

The DA01 Blood Glucose Test Strips are used with the DA01 Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the finger and the palm.

The DA06 Glucose Control Solutions are for use with the DA01 Blood Glucose Monitoring System as a quality control check that the meter and test strip are working together properly, and that the test is performing correctly.

3. Special conditions for use statement(s):

   For over-the-counter use

   Not for neonatal use, not for screening or diagnosis of diabetes mellitus.

   Not for use on critically ill patients, patients in shock, severely hypotensive individuals, dehydrated patients or individuals experiencing hyperglycemic-hyperosmolar state, with or without ketosis.

   For *in vitro* diagnostic use only.

   Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.

   AST testing should only be done during steady-state times (when glucose is not changing rapidly).

   For single-patient use only

4. Special instrument requirements:

   DA01 Blood Glucose meter

I. Device Description:

The DA01 Blood Glucose Monitoring System consists of the DA01 Blood Glucose meter, DA01 Blood Glucose Test Strips and three levels (levels I, II and III) of DA06 Control Solutions.

The DA01 Blood Glucose meters are Auto-Coding meters.

The DA06 Glucose Control Solutions are red aqueous solutions available at three levels. Control solution level II is included with the BGMS kit.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Glucose Shepherd Blood Glucose Monitoring System

2. Predicate 510(k) number(s):

   k102316

3. Comparison with predicate:

   The DA01 Blood Glucose Monitoring System has the following similarities and differences to the predicate device:

Item	Predicate Device Glucose Shepherd Blood Glucose Monitoring System (k102316)	Candidate Device DA01 Blood Glucose Monitoring System (k120866)
Indications for Use	Intended for use in the quantitative measurement of glucose in fresh capillary whole blood as an aid in monitoring the effectiveness of diabetes control program	Same
Testing Sites	Finger, palm, forearm, upper-arm, calf and thigh	finger and palm
Enzyme	Glucose Oxidase	Same
Measurement principle	Amperometric method	Same
Coding	No coding	Autocoding
Power	Two 1.5V AAA alkaline batteries	Two 3V CR2032 batteries
Test range	20 mg/dL to 600 mg/dL	Same
Hematocrit	20% to 60%	30 to 55%
Operating conditions	50ºF to 104ºF (10ºC to 40ºC), below 85% R.H.	50ºF to 104ºF (10ºC to 40ºC), 20 to 90% R.H.
Strip storage conditions	39.2ºF to 104ºF (4ºC to 40ºC), below 85% R.H.	39 to 86 ºF (4 to 30 ºC), 20 to 75% R.H
PC link	available	Available but not active (the software was not evaluated in this submission)
Weight	53g with batteries	90g with batteries
Dimension	95mm (L) x 64mm (W) x 29mm (H)	85.5mm (L) x 64.5mm (W) x 23.1mm (H)
Test time	5 seconds	Same
Test volume	1.1 µL	1.0 µL
Memory	400 test results with day and	512 test results with day and

Item	Predicate Device Glucose Shepherd Blood Glucose Monitoring System (k102316)	Candidate Device DA01 Blood Glucose Monitoring System (k120866)
	time	time
Glucose units	Either mg/dL or mmol/L	mg/dL
AC/PC mode	Yes	Same

K. Standard/Guidance Document Referenced (if applicable):

CEN 13640 Stability Testing of *In Vitro* Diagnostic Reagents

CLSI EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline

CLSI EP6-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

IEC 62301 Medical Device Software – Software life cycle processes (software/informatics)

ISO 14971 Application of risk management to medical devices

ISO 15197 *In vitro* diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

L. Test Principle:

The DA01 Blood Glucose Monitoring System uses an electrochemical method. It is based on the quantitative measurement of glucose in whole blood using amperometric method, which detects the current produced from glucose oxidation. Glucose in the sample mixes with specific chemicals on the test strip producing a small amount of electrical current. The meter measures the current, as well as other important parameters, such as ambient temperature, and displays the corresponding blood glucose level in the sample. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The repeatability study was performed using heparin anti-coagulated whole blood (hematocrit adjusted within 42±2%) at five different glucose concentrations. The final glucose concentrations for the blood sample were confirmed by YSI 2300. Each sample was tested on twelve meters using three lots of test strips (lot A, meters 1~4; lot B, meters 5~8; lot C, meters 9~12). Ten measurements were obtained per meter and test strip vial, and glucose concentration (N=120 per concentration level). The results are summarized below:

Repeatability summary

	Level 1	Level 2	Level 3	Level 4	Level 5
YSI (mg/dL)	49.6	88.6	148	229	326
Overall mean (mg/dL)	51.70	90.11	140.62	225.13	336.13
Overall SD (mg/dL)	1.47	2.64	6.04	9.97	5.22
Overall CV (%)	2.84	2.93	4.29	4.43	1.55

Intermediate precision studies were performed using three levels of control solutions. Each sample was tested on ten meters with test strips from two test strip vials from each of the three lots of test strips (10 meters with each of the three test strip lots) for ten days (N=300 per concentration level).

Intermediate Precision summary

Control Solutions	Level 1 (30~50 mg/dL)	Level 2 (96~144 mg/dL)	Level 3 (280~420 mg/dL)
Overall mean (mg/dL)	48.19	142.78	350.84
Overall SD (mg/dL)	2.75	5.30	14.58
Overall CV (%)	5.72	3.72	3.32

b. Linearity/assay reportable range:

Nine EDTA venous blood samples were spiked with glucose stock solution (20% glucose solution) and tested. The samples ranged from 18.3 to 613 mg/dL(18.3, 40.8, 65.1, 103, 161, 256, 347, 524 and 613 mg/dL), with hematocrit adjusted within 42±2%, were confirmed by the YSI-2300. The study was performed using ten calibrated meters and one vial of test strips from each of the three lots in singlicate (N=10 per test strip lot per sample). The results are summarized below:

Linear relationship between DA01 BGMS and YSI 2300 in three lots of strips

Lot number	Linear relationship between DA01 and YSI 2300	Slope (95% CI)	Intercept (95% CI)
Lot 1	Y = 1.0616X - 5.4056, R^2=0.9992	1.0353 ~ 1.0878	-13.6048 ~ 2.7935
Lot 2	Y =1.0436X - 6.7097, R^2=0.9989	1.0133 ~ 1.0740	-16.1876 ~ 2.7683
Lot 3	Y = 1.0439X - 5.6241, R^2=0.9989	1.0131 ~ 1.0747	-15.2559 ~ 4.0077
Combined	Y = 1.0497X - 5.9131, R^2=0.9991	1.0212 ~ 1.0782	-14.8155 ~ 2.9892

The measurement range of the DA01 Blood Glucose Monitoring Systems is 20 to 600 mg/dL.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

DA06 Control Solutions:

Traceability and value assignment – The DA06 control solutions are traceable to the N.I.S.T SRM 917c and the YSI-2300 analyzer. Value assignment was performed

with one DA06 glucose meter using test strips from one batch and three levels of control solutions (from two lots). Each level of control solution was tested 25 times. The mean, standard deviation and CV are calculated for each new lot of control material. If the three CVs are <5%, then the control range for each strip lot is calculated as mean ± 22% (for mean value ≥75 mg/dL) and mean ± 15 mg/dL (for mean value <75 mg/dL). The range is confirmed using the second lot of control solution.

Stability - Open vial control stability was tested at three control levels on three lots. Based on these studies, open vial stability is 90 days when stored tightly closed at temperatures between 39°F and 86°F (4°C and 30°C). An accelerated study for unopened vial control stability was performed on three lots each of the three control levels. Real time stability studies are ongoing. Unopened control solutions were tested under identical conditions as the opened control solutions. The unopened control solutions have an 18 month shelf life when stored at 39°F to 86°F (4°C to 30°C). Stability studies protocol and acceptance criteria for open and unopened vials were provided and found to be adequate.

DA01 Blood Glucose Test Strips:

Stability – Accelerated and ongoing real-time stability studies were performed for DA01 Blood Glucose test strips to assess the shelf-life and open-vial stability of the test strips. Stability study protocol and acceptance criteria were provided and found to be adequate. The sponsor claims the stability of unopened test strip vials as 18 months and of opened test strip vials as 3 months when stored at temperatures between 39°F to 86°F (4°C to 30°C) at 20 to 75% R.H.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on the linearity/assay reportable range study above (section M.1.b).

e. Analytical specificity:

Interference study was designed according to CLSI EP7-A2 guideline. Thirty three potential endogenous and exogenous interfering substances were evaluated by spiking NaF venous blood (HCT 42±2%) with two levels of glucose concentrations within the ranges 50 to 80 mg/dL and 110 to 150 mg/dL. The glucose samples were spiked with the potentially interfering compounds and tested on ten meters using one test strip lot. Several concentrations of the interfering substances were tested as shown in the table below. Bias was calculated as individual percent difference in glucose reading between the test and control concentration groups. Significant interference is defined by the sponsor as a bias >10 % of the test samples from the control group.

The sponsor claims no significant interference (≤ 10% difference) for the substances and concentrations shown in the table below:

Interferent	Therapeutic Concentration	Highest Concentration tested with no significant interference
Exogenous Substances		
Acetaminophen	1.0~3.0 mg/dL	6.0 mg/dL
Ascorbic acid	0.4~2.0 mg/dL	3.0 mg/dL
Dopamine	0.03 mg/dL	1.25 mg/dL
Gentisic acid	0.2~0.6 mg/dL	2.5 mg/dL
Ibuprofen	1.0~7.0 mg/dL	50 mg/dL
Levo-Dopa	0.3 mg/dL	2.0 mg/dL
Methyl Dopa	0.1~0.75 mg/dL	1.5 mg/dL
Salicylic acid	10~30 mg/dL	60 mg/dL
Tetracycline	0.2~0.5 mg/dL	1.5 mg/dL
Tolazamide	1.86~2.49 mg/dL	8.5 mg/dL
Tolbutamide	5.4~10.8 mg/dL	65 mg/dL
Sodium Chloride	135~145 mmol/L	175 mmol/L (mEq/L)
Maltose	99~120 mg/dL	1000 mg/dL
Pseudoephedrine		10 mg/dL
Endogenous Substances		
	Reference Interval	
Uric acid	2.5~8.0 mg/dL	9 mg/dL
Bilirubin	0.3~1.2 mg/dL	25 mg/dL
Creatinine	0.6~1.3 mg/dL	13 mg/dL
Cholesterol	114~201 mg/dL	550 mg/dL
Triglyceride	29.8~324.6 mg/dL	2200 mg/dL
Urea	6.6~85.8 mg/dL	260 mg/dL
Hemoglobin	100~200 mg/dL	650 mg/dL
Sugars		
Galactose		1000 mg/dL
Lactose		1000 mg/dL
Mannose		1000 mg/dL
Xylose		1000 mg/dL
Sugar Alcohols		
Mannitol		1000 mg/dL
Sorbitol		1000 mg/dL
Lactitol		1000 mg/dL
Xylitol		1000 mg/dL
Maltitol		1000 mg/dL
Isomalt		1000 mg/dL

Interference was observed with the following substances at concentrations above the limiting concentrations shown below:

Interferent	Limiting Concentration (mg/dL)	Concentrations tested (mg/dL)
Acetaminophen	6.0	3.0, 6.0, 9.0, 12.0
Dopamine	1.25	1.25, 2.5, 3.75, 5.0
Gentisic acid	2.5	2.5, 5.0, 7.5, 10
Levo Dopa	2.0	2.0, 4.0, 6.0, 8.0
Methyl Dopa	1.5	0.5, 1.0, 1.5, 2.0
Uric acid	9.0	4.3, 9.08, 13.85, 18.63, 23.4

Hemoglobin	650	100, 375, 650, 925, 1200

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Accuracy Study using the DA01 Blood Glucose Monitoring System: The study was performed by three healthcare professionals using capillary whole blood from finger and palm, and EDTA venous blood samples from 120 patients. An additional twelve samples (<50 mg/dL and >400 mg/dL) were prepared by manipulation of blood samples. The samples were tested using one lot of DA01 test strips and two DA01 glucose meters. Distribution of glucose concentrations across the measuring range was: 6 samples <50 mg/dL, 17 samples between 50 to 80 mg/dL, 25 samples between 81 to 120 mg/dL, 36 samples between 121 to 200 mg/dL, 18 samples between 201 to 300 mg/dL, 12 samples between 301 to 400 mg/dL and 6 samples >400 mg/dL. All results were compared to the venous blood samples (EDTA) tested by clinical chemistry analyzer (Hitachi model 7070). The studies met the ISO 15197 accuracy criteria, i.e. 95% of glucose results <75 mg/dL were within ± 15 mg/dL, and for samples ≥75 mg/dL, 95% of results were within ± 20% of the reference method. Results are summarized below:

Regression Analysis: Professional testing on DA01 BGMS vs. clinical chemistry analyzer (Hitachi model 7070)

Test Site / Meter	**Regression Equation**	**Standard Error**	**Slope (95% CI)**	**Intercept (95% CI)**
Finger / Meter1	Y = 0.9628X -2.1701, R2 = 0.9758	17.031	0.990 ~ 0.935	-7.852 ~ 3.511
Finger / Meter2	Y = 0.9581X-3.0521, R2 = 0.9766	16.632	0.931 ~ 0.985	-8.601 ~ 2.496
Palm/ Meter1	Y = 0.9702X-3.6487, R2 = 0.9750	17.440	0.942 ~ 0.999	-9.467 ~ 2.169
Palm/ Meter2	Y = 0.9638X-2.3855, R2 = 0.9756	17.097	0.936 ~ 0.992	-8.090 ~ 3.318

Healthcare Professional testing on DA01 BGMS vs. clinical chemistry analyzer (Hitachi model 7070) at glucose concentration <75 mg/dL

Test Site / Meter	Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger / Meter1	14/22 (63.6%)	22/22 (100%)	22/22 (100%)
Finger / Meter2	15/22 (68.2%)	21/22 (95.5%)	22/22 (100%)
Palm/ Meter1	11/22 (50%)	19/22 (86.4%)	22/22 (100%)
Palm/ Meter2	15/22 (68.2%)	21/22 (95.5%)	21/22 (95.5%)

Healthcare Professional testing on DA01 BGMS vs. clinical chemistry analyzer (Hitachi model 7070) at glucose concentration ≥75 mg/dL

Test Site / Meter	Within ± 5%	Within ± 10%	Within ± %15	Within ± 20%
Finger / Meter1	30/98 (30.6%)	69/98 (70.4%)	85/98 (86.7%)	96/98 (98.0%)
Finger / Meter2	32/98 (32.7%)	65/98 (66.3%)	85/98 (86.7%)	94/98 (95.9%)
Palm/ Meter1	29/98 (29.6%)	65/98 (66.3%)	86/98 (87.8%)	95/98 (96.9%)
Palm/ Meter2	32/98 (32.7%)	65/98 (66.3%)	85/98 (86.7%)	94/98 (95.9%)

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

User Performance Study:

The Method Comparison and alternative site testing study for fingerstick and palm was performed first by lay user, and then followed by healthcare professional. The lay user utilized fresh capillary blood samples from fingerstick and palm in a glucose steady state, while the healthcare professional collected venous blood samples in heparin tubes for comparison with reference method. One hundred and fifty six patients participated in the study. Labeling was provided only in English and users followed it to perform testing. The samples were tested using three lots of DA01 test strips. All results were compared to the YSI. The studies met ISO 15197 accuracy criteria, e.g. 95% of glucose results < 75 mg/dL were within ± 15 mg/dL, and for samples ≥ 75 mg/dL, 95% of results were within ± 20% of the reference method. Results are summarized below:

Regression analysis: Lay user testing on DA01 BGMS vs. the clinical chemistry analyzer (Hitachi model 7070)

Lot No. / Test Site	**Regression Equation**	**Standard Error**	**Slope (95% CI)**	**Intercept (95% CI)**
Lot A / Finger	Y = 0.9737X -4.1593, R2 = 0.9794	11.819	0.933 ~ 1.015	-11.000 ~ 2.681
Lot B / Finger	Y = 0.9521X-1.2478, R2 = 0.9513	13.942	0.890 ~ 1.105	-11.348 ~ 8.852
Lot C / Finger	Y = 0.9509X-0.3923, R2 = 0.9586	13.804	0.894 ~ 1.008	-10.349 ~ 9.565
Combined lots	Y = 0.9614X-2.3503, R2 = 0.9660	13.071	0.932 ~ 0.991	-7.256 ~ 2.556

/ Finger				
Lot A / Palm	Y = 0.9687X-2.7650, R2 = 0.9757	12.784	0.924 ~ 1.013	-10.165 ~ 4.634
Lot B / Palm	Y = 0.9492X-0.2746, R2 = 0.9527	13.680	0.888 ~ 1.011	-10.184 ~ 9.635
Lot C / Palm	Y = 0.9574X-3.1068, R2 = 0.9585	13.914	0.900 ~ 1.015	-13.144 ~ 6.930
Combined lots / Palm	Y = 0.9592X-2.1734, R2 = 0.9645	13.327	0.929 ~ 0.989	-7.176 ~ 2.829

Lay user testing on DA01 BGMS vs. clinical chemistry analyzer (Hitachi model 7070) at glucose concentration <75 mg/dL

Lot No. / Test Site	Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot A / Finger	4/9 (44.4%)	8/9 (88.9%)	9/9 (100%)
Lot B / Finger	3/4 (75.0%)	3/4 (75.0%)	4/4 (100%)
Lot C / Finger	4/5 (80.0%)	5/5 (100%)	5/5 (100%)
Combined lots / Finger	11/18 (61.1%)	16/18 (88.9%)	18/18 (100%)
Lot A / Palm	6/9 (66.7%)	8/9 (88.9%)	9/9 (100%)
Lot B / Palm	2/4 (50.0%)	3/4 (75.0%)	4/4 (100%)
Lot C / Palm	1/5 (20.0%)	5/5 (100%)	5/5 (100%)
Combined lots / Palm	9/18 (50.0%)	16/18 (88.9%)	18/18 (100%)

Lay user testing on DA01 BGMS vs. clinical chemistry analyzer (Hitachi model 7070) at glucose concentration ≥75 mg/dL

Lot No. / Test Site	Within ± 5%	Within ± 10%	Within ± %15	Within ± 20%
Lot A / Finger	14/41 (34.1%)	25/41 (61.0%)	32/41 (78.0%)	39/41 (95.1%)
Lot B / Finger	15/46 (32.6%)	29/46 (63.0%)	38/46 (82.6%)	44/46 (95.7%)
Lot C / Finger	18/45 (40.0%)	32/45 (71.1%)	41/45 (91.1%)	45/45 (100%)
Combined lots / Finger	47/132 (35.6%)	86/132 (65.2%)	111/132 (84.1%)	128/132 (97.0%)
Lot A / Palm	12/41 (29.3%)	24/41 (58.5%)	31/41 (75.6%)	39/41 (95.1%)
Lot B / Palm	15/46 (32.6%)	31/46 (67.4%)	41/46 (89.1%)	45/46 (97.8%)
Lot C / Palm	11/45 (24.4%)	32/45 (71.1%)	38/45 (84.4%)	43/45 (95.6%)
Combined lots / Palm	38/132 (28.8%)	87/132 (65.9%)	110/132 (83.3%)	127/132 (96.2%)

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Expected blood glucose values for normal people without diabetes is cited from the literature[1] and presented in the labeling as follows:

   Fasting and before meal: <100 mg/dL
   2 hours after meal: Less than <140 mg/dL

   [1]Standards of Medical Care in Diabetes (2012), ADA, I. Classification and Diagnosis. Diabetes Care 2012; 35(suppl 1): S 13. Table3.

N. Instrument Name:

DA01 Blood Glucose meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 1.0 µL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No ___X_____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes _____X___ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger and the palm. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The DA01 Blood Glucose meter is an autocoding device.

6. Quality Control:

   Glucose control solutions at three concentration levels can be run with this device. The meter has to be set in control solution test mode to prevent control results from being stored in the internal memory as patient result. Recommendations on when to test the control materials are provided in the labeling. The control solution results are not included in the average of the patient results. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges. Control solution level II is included with the DA01 Blood Glucose Monitoring System kit. Control solution level I and III can be purchased separately.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. A usability study was performed to assess the readability of the labeling by recruiting 150 lay users (aged 15-80 yrs old) who were provided with the test kit containing labeling in English for the US market. Participants varied in age, education, and both men (n = 66) and women (n = 84) were included in the study. These lay users completed a questionnaire to indicate whether the device is easy to use and all labeling (user manual, quick reference guide and test strip package insert) were written in a way that makes it easy to use. The majority of the users responded that the device is easy to use and the labeling is clear and easy to understand.
2. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User Guide, quick reference guide, and test strip package insert) were written at grade levels ranging from 5.0^{th} to 7.0^{th} grade.
3. Customer service is available Monday to Friday between 9:00 AM to 5:00 PM EST. The telephone number is 1-855-933-5246 for customer support. The users are advised to contact their healthcare professionals at all other times.
4. The effect of different hematocrit levels on the accuracy of the device was evaluated on the DA01 Blood Glucose Monitoring System using ten meters (tested in ten replicate) and one lot of test strips. Venous blood (heparinized) samples at eight hematocrit levels from 25% to 60% (25, 30, 35, 40, 45, 50, 55 and 60%) were evaluated in three concentrations of glucose of approximately 57, 107 and 325 mg/dL. Individual glucose concentration results were compared to YSI values as well as to the glucose concentration results on the meter at the normal HCT (40%). Individual percent bias was calculated. No significant interference from hematocrit was defined as individual percent bias ≤15%. Results demonstrated that hematocrit levels between 30 to 55% do not significantly interfere with glucose measurements on the DA01 BGMS.
5. Insufficient sample studies were performed at volumes starting from 0.6 µL to 1.5 µL in increments of 0.1 µL around the recommended volume (1.0 µL) using ten meters and three lots of test strips. Each sample was tested ten times per strip lot. Three glucose concentration levels of venous whole blood were tested (66 mg/dL, 138 mg/dL and 352 mg/dL) as determined by the YSI. Appropriate sample volume was determined if the meter results compared to YSI results were within 10% bias for blood samples. A blood volume ≥ 0.8 µL met the criteria.
6. Temperature and humidity operating conditions were evaluated for temperatures ranging from 48.2°F to 105.8°F (9°C to 41°C) and relative humidity ranging from 20% to 91% R.H. The extremes of both temperature and humidity were tested in combinations of low temperature with low and high humidity, and of high temperature with low and high humidity. The claimed operating temperature range is 50 °F to 104 °F and humidity range is 20 to 90%RH.
7. The DA01 meter was tested for its reliability to high and low temperature conditions, humidity conditions, and vibration and drop testing. The meter performance and functions were not affected after the standard vibration and drop tests. The meter was also shown to withstand temperatures 55±2°C and -20±2°C at 60% RH for 8 hours, and humidity condition of 93±3% at 32±2°C for 48 hours.

8. The effect of altitude on the accuracy of the device was evaluated on the DA01 Blood Glucose Monitoring System with ten meters and three lots of test strips using venous blood (NaF) samples at six glucose levels (50~70 mg/dL, 71-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL, 401-600 mg/dL; HCT within 42±2). Individual meter results at altitude >9000 feet was compared to the YSI values. Individual percent bias was calculated. No significant interference from high altitude was defined as individual percent bias ≤10%. Results demonstrated that altitudes ≤9000 feet do not significantly interfere with the glucose measurements on the DA01 BGMS.
9. The DA01 Blood Glucose Monitoring System is intended for home use by a single person. Disinfection studies were performed on the DA01 meter to determine the robustness of the meter to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV). Super Sani-cloth germicidal disposable wipes manufactured by Professional Disposables International, Inc. (EPA Reg. No. 9480-4) were validated, demonstrating complete inactivation of live virus for use with the DA01 meter. The sponsor demonstrated that there was no change in performance or in the external materials of the DA01 meter after 260 cleaning and disinfection cycles to simulate an estimated one cleaning and disinfection cycles per week over 5 years of use at home by a single person. Labeling has been reviewed for adequate instructions on the validated cleaning and disinfection procedures.
10. EMC testing was evaluated and certified by SGS Taiwan Ltd., and a certificate of conformity was issued to Delbio Incorporation on February 16, 2012.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.